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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Vibeke Nissen

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EXAMINER

DEES, NIKKI H

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/520,173	<b>Applicant(s)</b> NISSEN, VIBEKE	
	<b>Examiner</b> Nikki H. Dees	<b>Art Unit</b> 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,8-12,14-19 and 28-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,8-12,14-19 and 28-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>25 June 2009</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicant's amendment filed on October 26, 2009, has been entered. Claims 1, 3-5, 8-12, 14-19, and 28-32 are currently pending in the Application. Claims 2 and 6 have been cancelled. The previous 112 rejections of claims 10 and 12 have been withdrawn in view of Applicant's arguments. The previous 112 rejection of claim 16 has been withdrawn in view of the amendment to claim 16.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3-5, 8-12, 14-19 and 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cherukuri et al. (4,753,805) in view of Hinzpeter et al. (5,643,630).

4. Cherukuri et al. teach compressed chewing gum tablets having a water content of about 2% and a method for making them. A chewing gum composition is prepared including gum base granules composed of natural and synthetic resin and elastomers in an amount ranging from 14 to 50 wt % (col. 6 lines 14-24), flavors in an amount ranging from 0.05 to 3 wt % (col. 8 lines 14-34), natural resins (e.g. rosin esters) including

Art Unit: 1794

glycerol esters of polymerized rosin in an amount ranging from about 10 to 75 wt % (col. 6 lines 24-42), sweeteners ranging in an amount from about 0.001 to 90 wt % depending on the sweetener selected (col. 6 line 52-col. 7 line 21), plasticizer and active ingredients (col. 9 lines 14-29), and optionally wax (col. 7 lines 36-40). The amounts taught for these components substantially overlap with the amounts claimed by Applicants. The flavorings and active agents are mixed (teared) into the gum-base composition prior to compression (Example I; col. 8 lines 14-29).

5. The granules are compressed into tablets. Magnesium stearate is present in the compressed tablets as a lubricant (col. 5 lines 1-10). The lubricant is added following the granulation of the gum center (Example II). The lubricant aids in granulation by facilitating removal from the mold, reducing the wear on the dies and punches, and minimizing the potential for capping (col. 4 lines 34-60).

6. Regarding claim 1, Cherukuri et al. are silent as to the "improved and sticky" texture of the tablet resulting from the inclusion of the natural resin. However, as the invention of Cherukuri et al. comprises the same ingredients as claimed by Applicants in substantially similar amounts, this improved texture would have been expected to be present in the invention of Cherukuri et al. absent convincing arguments or evidence to the contrary.

7. Cherukuri et al. are silent as to the gum center being encapsulated by the barrier layer.

8. Hinzpeter et al. teach compressed tablets comprising a lubricant wherein the lubricant is deposited directly on the tableting machine to facilitate the production of

Art Unit: 1794

tabletted materials and form a barrier layer on the tablet utilizing minimal amounts of lubricant (col. 1 lines 57-62). They teach their process as an improvement over the prior art, wherein the lubricants (e.g. magnesium stearate) were combined with the material to be compressed (col. 1 lines 33-40). Hinzpeter et al. teach their invention as an improvement of the prior art process as it requires less lubricant, requires less pressure for tableting, and reduces the wear on the compression tools (col. 2 lines 48-55). The barrier layer as taught by Hinzpeter et al. is provided during the manufacturing of the tablets (col. 2 lines 20-24).

9. One of ordinary skill in the art at the time the invention was made wishing to improve the compressed tablet of Cherukuri et al. the process by which it was made by providing a barrier layer using less magnesium stearate or other lubricant, would have found it obvious to employ the tableting method of Hinzpeter et al. for tableting the chewing gum of Cherukuri et al. in order to provide a tabletted chewing gum with a barrier layer while requiring less lubricant and reducing the wear on the production equipment. The use of magnesium stearate as a barrier layer for tabletted materials, as taught by Hinzpeter et al., instead of mixing with the granulated chewing gum material as taught by Cherukuri et al., would have been an obvious improvement of the prior art method at the time the invention was made. The barrier layer as taught by Hinzpeter et al. is provided during the manufacturing process. It is noted that the limitation of the barrier layer being provided during the manufacturing process is considered to be a product by process limitation and does not determine the patentability of the chewing

Art Unit: 1794

gum product. In any event, Hinzpeter et al. teach forming the barrier layer during tableting.

10. Claims 1, 3-5, 8-12, 14-19 and 28-32 rejected under 35 U.S.C. 103(a) as being unpatentable over Yang (EP 0 221 850) in view of Hinzpeter et al. (5,643,630).

11. Yang teaches compressed chewing gum tablets having a water content of about 2% and a method for making them. A chewing gum composition is prepared including gum base granules composed of natural and synthetic resin and elastomers (col. 8 lines 47-58)), flavors in an amount ranging from about 1 to 10 wt % (col. 10 lines 30-55), natural resins (e.g. rosin esters) including glycerol esters of polymerized rosin in an amount ranging from about 10 to 75 wt % of the gum base (col. 8 line 59-col. 9 line 13), sweeteners ranging in an amount from about 0.001 to 98 wt % depending on the sweetener selected (col. 9 lines 29-65), plasticizer and active ingredients (col. 7 line 58-col. 8 line 19), and optionally wax (col. 9 lines 14-26). The amounts taught for these components substantially overlap with the amounts claimed by Applicants. The flavorings and active agents are mixed (teared) into the gum-base composition prior to compression (col. 11 lines 28-37).

12. The granules are compressed into tablets. Magnesium stearate is present in the compressed tablets as a lubricant. The lubricant aids in the tableting by facilitating removal from the mold, reducing the wear on the dies and punches, and easing the ejection of the tablet from the die (col. 10 lines 3-23).

13. Regarding claim 1, Yang is silent as to the "improved and sticky" texture of the tablet resulting from the inclusion of the natural resin. However, as the invention of Yang comprises the same ingredients as claimed by Applicants in substantially similar amounts, this improved texture would have been expected to be present in the invention of Yang absent convincing arguments or evidence to the contrary.

14. Yang is silent as to the gum center being encapsulated by the barrier layer.

15. Hinzpeter et al. teach compressed tablets comprising a lubricant wherein the lubricant is deposited directly on the tableting machine to facilitate the production of tabletted materials and form a barrier layer on the tablet utilizing minimal amounts of lubricant (col. 1 lines 57-62). They teach their process as an improvement over the prior art, wherein the lubricants (e.g. magnesium stearate) were combined with the material to be compressed (col. 1 lines 33-40). Hinzpeter et al. teach their invention as an improvement of the prior art process as it requires less lubricant, requires less pressure for tableting, and reduces the wear on the compression tools (col. 2 lines 48-55). The barrier layer as taught by Hinzpeter et al. is provided during the manufacturing of the tablets (col. 2 lines 20-24).

16. One of ordinary skill in the art at the time the invention was made wishing to improve the compressed tablet of Yang, and the process by which it was made, would have found it obvious to employ the tableting method of Hinzpeter et al. for tableting the chewing gum Yang in order to provide a tabletted chewing gum with a barrier layer while requiring less lubricant and reducing the wear on the production equipment. The use of magnesium stearate as a barrier layer for tabletted materials, as taught by

Art Unit: 1794

Hinzpeter et al., instead of mixing with the granulated chewing gum material as taught by Yang, would have been an obvious improvement of the prior art method at the time the invention was made. The barrier layer as taught by Hinzpeter et al. is provided during the manufacturing process. It is noted that the limitation of the barrier layer being provided during the manufacturing process is considered to be a product by process limitation and does not determine the patentability of the chewing gum product. In any event, Hinzpeter et al teach forming the barrier layer during tableting.

### ***Double Patenting***

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 1-6, 8-12, 14-19 and 28-32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20



and 34 of copending Application No. 10/520,387. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to use the barrier layer in the claims of 10/520,387 to either partially or fully encapsulate the claimed gum tablet simply depending upon desired results, consumer appeal and personal preference.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. Claims 1-6, 8-12, 14-19 and 28-32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-55 of copending Application No. 11/028,684 in view of Cherukuri et al or Yang. It would have been obvious to include magnesium stearate as an outer barrier layer in the gum tablets claimed in 11/028,684 since magnesium stearate is a conventional lubricant used in gum tablets, as evidenced by either secondary reference and since it would have been obvious to include the magnesium stearate as the outer layer of the tablets as set forth in the rejections *supra*.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Response to Arguments***

20. Applicant's arguments filed October 26, 2009, have been fully considered but they are not persuasive.

21. Applicant argues that Hinzpeter et al. is non analogous art (Remarks, p. 11) and would not have been consulted by one of ordinary skill in the chewing gum art.

22. In response to applicant's argument that Hinzpeter et al. is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Cherukuri et al. and Yang et al. are in the field of tabletted chewing gums, and Hinzpeter et al. is in the field of tableting materials. As Hinzpeter et al. speak to lubricants commonly used in tableting devices, such as those that would have been used in tableting chewing gums, all of the references are considered to be pertinent to the particular problem with which Applicant was concerned.

23. Applicant argues (Remarks, pp. 12-13) that there is no indication in either Cherukuri et al. or Yang et al. that a barrier layer would improve the compressed chewing gum tablets.

24. In response to applicant's argument that Cherukuri et al. and Yang et al. do not speak to a barrier layer of lubricant improving the compressed tablets, the fact that

Art Unit: 1794

applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

25. As noted in the teachings of Hinzpeter, a barrier layer in the tableting process would have been expected to reduce the amount of lubricant (i.e. stearates) used in the tablet, as well as reduce the wear on the tableting machinery. While the prior art may not have recognized the effects on the texture of the chewing gum, as noted by the instant invention, there is motivation in the prior art to modify the tableting process.

26. Applicant also appears to be arguing against the references individually, in not recognizing the contribution of Hinzpeter et al. to the distribution of the barrier layer in the tablet (Remarks, pp. 12-13).

27. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

28. Arguments against Cherukuri et al. and Yang et al. where the texture of their chewing gum compositions would not be the same are not persuasive as the arguments do not take into consideration that the combination of Cherukuri et al. or Yang et al. with Hinzpeter et al. provides for the barrier layer to be encapsulating the chewing gum

portion, not mixed in with the gum components. Both Cherukuri et al. and Yang et al. disclose stearates as the lubricating materials.

29. Applicant argues that Cherukuri does not disclose any gum base granules, nor does Cherukuri disclose an example of a gum base or chewing gum composition comprising a natural resin (Remarks, p. 16).

30. The examiner notes Table 1 of Cherukuri disclosing a composition comprising gum base which is granulated. At col. 6 lines 25-42 Cherukuri et al. disclose elastomer solvents for use in their invention, including natural resins as specifically required in Applicant's claim 15. It is further noted that these resins, which Cherukuri et al. refers to as elastomer solvents, are well known and widely utilized in the chewing gum art. While Cherukuri et al. do not disclose the exact composition of the gum base in Table 1, the inclusion of these natural resins in the gum base is clearly taught.

31. It is noted that the double-patenting rejections are not addressed in the Remarks other than to indicate Terminal Disclaimers may be filed if deemed appropriate in the future.

### ***Conclusion***

32. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikki H. Dees whose telephone number is (571) 270-3435. The examiner can normally be reached on Monday-Friday from 7:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks, can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

Art Unit: 1794

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/N. H. D./  
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